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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,802	09/10/2003	Patrick Fogarty	TOSK-007CON	5245

24353 7590 05/18/2006

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EXAMINER

MONTANARI, DAVID A

ART UNIT PAPER NUMBER

1632

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,802	FOGARTY, PATRICK	
	Examiner	Art Unit	
	David Montanari	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-18 and 27-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-18, 27-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants arguments and amendments filed 2/27/2006 have been entered.
2. Claims 11-18, 27, and 31 have been amended.
3. Claims 35-41 are newly added.
4. Claims 1-10, and 19-26 are cancelled.
5. Rejection of claims 11-17, 27-29, and 31-33 under 35 USC 101 is withdrawn.
6. Rejection of claims 11-18 and 27-34 under 35 USC 101 Statutory-Type double patenting is withdrawn.
7. Rejection of claims 1-17, 25, 31, and 36 under 35 USC 101 Obvious-Type double patenting is withdrawn.
8. Applicants Terminal Disclaimer filed 2/27/2006 has been approved.
9. Rejection of claims 11-18 and 27-34 under 35 USC 102(b) is withdrawn.
10. Rejection of claims 11-18 and 27-34 under 35 USC 102(b)/103(a) is withdrawn.
11. Claims 11-18, and 27-41 are examined in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12 and 35-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The instantly amended claims now contain the recitation "cell in vitro". However, the instant specification does not disclose any teachings that any in vitro work or conception to do in vitro work in a cell was contemplated at the time of filing. Thus claims 12 and 35-41 are rejected as new matter. Applicants are invited to point out page and line number where the instantly filed specification supports the new claim amendment.

Claims 11-18, and 27-34 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inserting an exogenous nucleic acid into the genome of a mouse, wherein said method comprises introducing into said mouse a P-element derived vector comprising a pair of P-element transposase recognized insertion sequences flanking at least one transcriptionally active gene that is at least 50 bp proximity to one of the P-element transposase recognized sequences and a transposase domain, and a method of inserting an exogenous nucleic acid into the genome of a mouse, wherein said method comprises introducing into said mouse a P-element derived vector comprising a pair of P-element transposase recognized insertion sequences flanking at least one transcriptionally active gene that is at least 50 bp proximity to one of the P-element transposase recognized sequences, wherein said method further comprises inserting a second P-element vector comprising a transposase domain, and cells from said mouse, does not reasonably provide enablement for a method of inserting an exogenous nucleic acid into the genome of any non-Drosophilidae animal, wherein said method comprises introducing into said non-Drosophilidae animal a P-element derived

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vector comprising said exogenous nucleic acid, and cells from said non-Drosophilidae animal.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons of record in the office action mailed 8/30/2005.

Response to Arguments

Applicants argue in amendment filed 2/27/2006 the present application provides sufficient disclosure to enable the invention to the full scope of the pending claims. Applicants continue to argue that methods were known to the skilled artisan at the time of filing to make transgenic frogs and transgenic zebrafish. Applicants continue that at the time of filing methods were known to the skilled artisan to overcome hurdles faced in generating transgenic animals using standard techniques and cites work utilizing inducible gene expression systems as support. Applicants continue that once transgenesis is demonstrated in one species, as detailed in the instant specification, it is reasonable to conclude that the methods could be extrapolated to other animals in a similar manner without undue experimentation. Applicants continue with a detailed break down of In re Wands Factors to highlight how the instantly filed specification supports the breadth of the claimed invention. This is not persuasive. The breadth of the claims encompasses all transgenic non-human and non-drosophilidae animals. Thus, the claims would encompass transgenic whales, transgenic fish, transgenic elephants etc. The instantly filed specification does not support such a breadth in the instant claims. The previous office action has detailed specifically that many issues remain that result in the highly unpredictable field of transgenesis

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in any organism. However, due to significant research in the mouse, the mouse is a model for transgenic research. Though the mouse is well characterized and studied for the purposes of transgenesis, this does not lead to a routine and easy extrapolation of science that will lead to the creation of all other transgenic non-human and non-drosophilidae animals. The art of record is clear, transgenesis in animals other than mouse is highly unpredictable. The art provided as evidence in applicants response, though supporting specific instances of transgenesis in frogs and zebrafish, does not indicate that transgenesis in those organisms is routine. Furthermore the genus of frogs is huge, and encompasses many divergent and unique species that would be beyond the teachings in the instant specification. Specific protocols and guidance is required for any organism to undergo transgenesis, and the instant specification provides no guidance for any animal other than mouse. Thus for reasons of record in the office action mailed 8/30/2005 and above the rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 12, 16, 27, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 12 are unclear. In the last line of claims 11 and 12 the recitation "to insert said exogenous nucleic acid is inserted into said genome" is not clear. Recommended language would be "to insert said exogenous nucleic acid into said genome".

Claims 16 recites the limitation "said animal" in reference to the non-human animal in claims 11. Claim 16 should read "said non-human animal". There is insufficient antecedent basis for this limitation in the claim.

Claims 27 recites the limitation "from said animal" in reference to some claim. It is not clear which claim, claim 27 is referring to, to recited the term "said animal". There is insufficient antecedent basis for this limitation in the claim.

Claims 31 recites the limitation "from said animal" in reference to some claim. It is not clear which claim, claim 31 is referring to, to recited the term "said animal". There is insufficient antecedent basis for this limitation in the claim.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 1-571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Montanari, Ph.D.



DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER